CHEMICAL MANUFACTURERS ASSOCIATION

November 18, 1985

TO : Vinylidene Chloride Program Panel

FROM : Robert R. Romano, Ph.D.

SUBJECT: EPA's Health Advisory on VDC

CMA is attempting to comment on the numerous Health Advisories presented to us from EPA. The Agency will use these advisories as the basis for proposing RMCLs and MCLs, and ultimately will issue final RMCLs and MCLs.

Enclosed is an EPA news release which explains this Safe Drinking Water Act action. I have also enclosed EPA's health advisory on VDC. Please review the advisory and provide your comments ~~by~~ December 5, 1985, directly to:

J. McDade
Dow Chemical USA
Inorganic Chemicals Department
2020 Willard H. Dow Center
Midland, MI 48640
(517) 636-1321

Mr. McDade is coordinating all VDC comments to eventually become part of the official CMA comment package.

If you have any questions, please do not hesitate to call me at (202) 887-1198.

cc: J. McDade
Ann Mason, CMA

NOTE: The November 13, 1985 Federal Register has EPA's final RMCLs, proposed MCLs and the new proposed RMCLs.

United States
Environmental Protection
Agency

Office of
Public Affairs (A-107)
Washington DC 20460

EPA

Environmental News

FOR RELEASE: FRIDAY, OCTOBER 11, 1985

Mike O'Reilly 382-5590

EPA ANNOUNCES DRINKING WATER STANDARDS AND MONITORING REQUIREMENTS

The U.S. Environmental Protection Agency announced today recommended maximum contaminant levels (RMCLs) and proposed maximum contaminant levels (MCLs) for a group of eight chemical compounds that could cause health problems if they are found in drinking water supplies at significant levels. The agency also proposed monitoring requirements for 51 additional compounds for public water systems.

Quantities of all of these compounds have be n found at very low levels in about one-fifth of drinking water supplies. However, they are sometimes found in groundwater at much higher levels. The agency's major concern is to control current and future contamination of groundwater.

Chemical compounds covered by the proposal are benzene, carbon tetrachloride, p-dichlorobenzene, 1,2-dichloroethane, 1,1-dichloroethylene, 1,1,1-trichloroethane, trichloroethylene and vinyl chloride. These chemicals are members of a group known as volatile synthetic organic chemicals (VOCs), which are manufactured in hundreds of millions of pounds per year.They are industrial chemicals, degreasing agents, and dry cleaning fluids.

The recommended maximum contaminant levels (RMCLs) are nonenforceable health goals. Under the Safe Drinking Water Act this is the first step in setting standards. Under the law, recommended levels must be set at a point that presents no risk to public health.

This action sets RMCLs for the chemicals based on the evidence indicating possible human cancer risk. RMCLs of zero are set for five of the chemicals which have sufficient human or animal vidence to b considere as probable carcinogens. The other thr e compounds--

1,1-dichloroethylene, 1,1,1-trichloroethane and p-dichlorobenzene are not carcinogens and are set at levels of .007, .2, and .75 milligrams per liter, respectively, based upon their chronic toxicity.

EPA's proposed maximum contaminant levels for the eight compounds will lead to enforceable standards. The MCLs are set as close to the RMCLs as possible based on health considerations, treatment technologies, cost, and other factors. Four of the eight compounds -- trichloroethylene, carbon t trachloride, 1,2-dichloroethane and benzene are proposed at levels of .005 miiligrams per liter (5 parts per billion); vinyl chloride is set at .001 milligrams per liter. The other three, 1,1-dichloroethylene, 1,1,1-trichloroethane, and p-dichlorobenzene are proposed at the same levels as the r commended maximum contaminant levels.

Approximately 1,300 community water systems would be expected to exceed th proposed MCLs. EPA estimates the capital cost to the nation for treatment would be $280 million. Annual operating costs for treatment to comply with the proposed rules is estimated at $2[illegible] million per year.

Effective and economical water treatment metho[illegible] are available to control VOCs. The treatment techniques include aeration and filtration through granular activated carbon.

In addition to RMCLs and MCLs for the eight VOCs, this rule also proposes monitoring procedures for other currently unregulated VOCs. Because similar analytical procedures for the eight VOCs can also measure numerous other chemicals at a small additional cost, monitoring regulations for approximately 51 other VOCs are included in this proposed rule.

Public comment on tetrachloroethylene, which was included in EPA's original RMCL proposal, was extended in order to strengthen that standard based on new scientific data. EPA will set the RMCL and propose MCL levels for this compound in the near future after public comments have been reviewed on the new data.

These chemicals constitute Phase I of EPA's four part program for revised drinking water regulations. Phase II, which is also being announced today, covers synthetic organic chemicals, inorganic chemicals and microbiological contaminants. Phase III regulations will cover radionuclides which will include limitations for the amounts of radioactive substances found in drinking water such as radon and uranium. Phase IV regulations will cover limits for the byproducts from the disinfection of water supplies such as produced through chlorination. Once completed, this four phase program will represent the most comprehensive, scientific-bas d regulatory program for drinking water to date.

The final RMCLs and the proposed MCLs will be published in the Federal Register in the near future. A 90 day comment period on the proposed MCLs will begin with the publication of the rule in the Federal Register.

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MCLs for the VOCs

o The MCLs are proposed as follows:

Compound	Proposed MCL (mg/l)	= ppb
Trichloroethylene	0.005	5
Carbon tetrachloride	0.005	5
Vinyl chloride	0.001	1
1,2-Dichloroethane	0.005	5
Benzene	0.005	5
1,1-Dichloroethylene	0.007	7
1,1,1-Trichloroethane	0.200	200
p-Dichlorobenzene	0.750	750

o Comment period is 90 days from publication.

o A public hearing will be held in Washington, D.C. in December, 1985.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, telephone (202) 382-7575.

RMCLs for the synthetic organic chemicals are proposed as follows:

SOC	Proposed RMCL (mg/l)
Acrylamide	zero
Alachlor	zero
Aldicarb, aldicarb sulfoxide and aldicarb sulfone	0.009
Carbofuran	0.036
Chlordane	zero
cis-1,2-Dichloroethylene	0.07
DBCP	zero
1,2-Dichloropropane	0.006
o-Dichlorobenzene	0.62
2,4-D	0.07
EDB	zero
Epichlorohydrin	zero
Ethylbenzene	0.68
Heptachlor	zero
Heptachlor epoxide	zero
Lindane	0.0002
Methoxychlor	0.34
Monochlorobenzene	0.06
PCBs	zero
Pentachlorophenol	0.22
Styrene	0.14
Toluene	2.0
2,4,5-TP	0.052
Toxaphene	zero
trans-1,2-Dichloroethylene	0.07
Xylene	0.44

- Comment period is 120 days from publication.
- A public hearing will be held in Washington, D.C. in January 1986.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph.D., Director, Criteria and Standards Division, Office of Drinking Water (WH-550), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, telephone (202) 382-7575.

- RMCLs for non-carcinogens are set based upon chronic toxicity data using Acceptable Daily Intake Levels (ADIs).

- RMCLs consider the total exposure from air, food and drinking water when data are available. Typically 20% of the ADI is allocated to drinking water.

- RMCLs have been proposed for Giardia and viruses in order to control for waterborne infectious disease which is still a significant problem in some water supplies that are inadequately treated. More than 80,000 cases have been reported between 1971 and 1980 and most of them are caused by viruses and Giardia.

- RMCLs for the inorganic chemicals are proposed as follows:

Contaminant	Proposed RMCL (mg/l)
Arsenic	0.050
Barium	1.5
Cadmium	0.005
Chromium	0.12
Copper	1.3
Lead	0.020
Mercury	0.003
Nitrate	10
Nitrite	1
Selenium	0.045
Asbestos	7.1 million long fibers per liter

- RMCLs for the microbiological parameters are zero for total coliforms, Giardia and viruses and 0.1 Nephelometric Turbidity Unit (NTU) for turbidity.

United States
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EPA

Environmental News

FOR RELEASE: FRIDAY, OCTOBER 11, 1985

Mike O'Reilly 382-5590

EPA PROPOSES NEW DRINKING WATER GOALS

The U.S. Environmental Protection Agency announced today it is proposing recommended maximum contaminant levels (RMCLs) for 37 chemical (plus 2 by-products) and 4 microbiological contaminants that could be harmful if found in the drinking water supplies at significant levels.

The proposed goals are the first step in restricting levels of chemical and biological contaminants sometimes found in drinking water sources. Twenty-six synthetic organic chemicals are covered in this proposal including PCB's (polychlorinated biphenyls) and numerous pesticides including aldicarb. PCB's are used as liquid coolant and insulating material in electrical equipment. Aldicarb is a highly toxic pesticide that has been found in some ground water in agricultural areas.

The proposed rule also covers 11 inorganic chemicals including lead and mercury.

The four microbiological contaminants covered by the proposed rule are coliforms, turbidity, Giardia and other viruses. These relate to bacteria and other organisms which may cause infection and disease from contaminated and inadequately treated drinking water.

"The proposed goals are a significant step in the process of protecting the nation's public h alth from drinking water contamination," said EPA Administrator Lee M. Thomas. "The quantities of these chemicals found in drinking water have generally been at very low levels, but they are sometimes found in surface waters and groundwaters at high levels. Our major conc rn is to control current contamination of groundwater and prevent futur contamination."

SL 063109

Waterborn inf ctious disease is still a significant problem in some water supplies that are inadequately treated. More than 80,000 cases have been reported between 1971 and 1982 and most of them are caused by viruses or Giardia, a parasite. EPA's major goal is to use proper treatment or other protections in all public water supplies to assure safety.

The recommended maximum levels are nonenforceable goals. Under the Safe Drinking Water Act this is the first step in setting standards. The law requires that recommended levels be set at a point which would r sult in no known or anticipated adverse health effects with an adequate margin of safety.

The chemicals are grouped according to the strength of the evidence that they cause cancer or other health risks. The three categories include: (1) known or probable human carcinogens, (2) possible human carcinogens and (3) non-carcinogens.

RMCLs for probable human carcinogens are being proposed at zero. The level for the second category are higher than zero, but are set at low levels in case future information increases the evidence of possible carcinogenicity The RMCLs for the third group are based upon chronic toxicity. In determining RMCLs, contamination from the chemicals in the air and the food chain is also taken into consideration.

Final standards would come later in the process with the setting of maximum contaminant levels (MCLs) if EPA decides they are needed based upon health considerations , treatment technologies, cost and other factors.

The proposed rule also contains health advisory type information on 28 chemicals for which RMCLs are proposed and 10 which are not being proposed. A treatment advisory is proposed for Legionella,(legionnaire's disease organism) although an RMCL for Legionella is not proposed at this time.

Effective water treatment methods are available to control the chemicals and contaminants covered by this proposed rule. The treatment techniques include aeration and filtration through granular activated carbon and other processing depending on the chemical. The four biological contaminants can be controlled through filtration and disinfection.

These chemicals and biological agents are Phase II in EPA's four part program for revised drinking water regulations. Phase I, which is also being announced today, covers eight volatile synthetic organic chemicals and monitoring requirements for an additional 51 unregulated VOCs. Phase III regulations will cover radionuclides which will include limitations for the amounts of radioactive substances found in drinking water such as radon and uranium. Phase IV regulations will cover limits for the byproducts from the disinfection of water supplies such as produced through chlorination. Once completed, this four phase program will represent the most comprehensive, scientific-based regulatory program for drinking wat r to date.

The proposed RMCLs will be published in the Federal Register in the near futur . A 120 day comment period will b gin with the publication of the proposed rule in the Federal Register.

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of 1,1-dichloroethylene over a concentration range of 0.03 to 1500 ug/l. Confirmatory analysis for 1,1-dichloroethylene is by mass spectrometry (Method 524.1. Volatile organic compounds in water by purge and trap gas chromatography/mass spectometry. U.S. EPA, 1985b). The detection limit for confirmation by mass spectometry is 0.2 ug/L.

VIII. TREATMENT

- Granular activated carbon (GAC) adsorption and aeration treatment technologies are available for the removal of 1,1-DCE from water and have been reported to be effective. Selection of individual or combinations of technologies to achieve chemical reduction must be based on a case-by-case technical evaluation and an assessment of the economics involved.

- Aeration has been shown to be effective in removing 1,1-DCE from water, based upon its carbon adsorption isotherm (Henry's Law Constant = 498 atm) and pilot and full-scale testing. The chemical was removed successfully from contaminated ground water at 12-14°C in an EPA pilot packed tower aerator containing 18 feet of 1-inch plastic saddle packing (ESE, 1984). The average percent removal varied with air-to-water volume ratio, from 90.6% to 99.99% at ratios of 5 to 80, respectively. Similarly, the concentration of 1,1-DCE in contaminated well water decreased from 122 ug/L to 4 ug/L (97%) using diffused aeration (ESE, 1984). Aeration was conducted in a pilot (1.5 inch diameter, 4-foot long) countercurrent glass column, using a 10-minute contact time and an air-to-water ratio of 4.

- Air stripping is an effective, simple and relatively inexpensive process for removing 1,1-DCE and other organics from water. However, the use of this process transfers the contaminant directly to the air stream. When considering use of air stripping as a treatment process, it is suggested that careful consideration be given to the overall environmental occurrence, fate, route of exposure and various hazards associated with the chemical.

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Where:

10 mg/kg/day = LOAEL

100 = uncertainty factor, appropriate for use with animal study

10 = uncertainty factor, conversion of LOAEL to NOAEL

*RRfD = Risk Reference Dose: estimate of daily exposure to the human population which appears to be without appreciable risk of deleterious non-carcinogenic effects over a lifetime of exposure

Step 2: Determination of Lifetime Health Advisory

$$\text{Lifetime HA} = \frac{(0.01 \text{ mg/kg/day})(70 \text{ kg})}{(2 \text{ L/day})} = 0.35 \text{ mg/L} = 350 \text{ ug/L}$$

Where:

0.01 mg/kg/day = RRfD

70 kg = assumed weight of protected individual

2 L/day = assumed volume of water ingested by 70 kg adult

The Lifetime Health Advisory of 350 ug/L derived above reflects an assumption that 100% of the exposure to 1,1-dichloroethylene is via the drinking water. It has been shown, however, that exposure might well occur via other routes. Since compound-specific data on actual relative source contribution are lacking, it may assumed that drinking water contributes 20% of an adult's daily exposure to this substance. The Lifetime Health Advisory for the 70 kg adult would be 70 ug/l, taking this relative source contribution into account.

Evaluation of Carcinogenic Potential

Qualitative and quantitative assessment of the carcinogenic potential of 1,1-dichloroethylene is complicated by the fact that the only positive data - mammary tumors in female rats and mice and kidney adenocarcinomas in mice-(Maltoni, 1977) have become finalized only recently. They have not yet been published, although they have been submitted for publication (Maltoni et al., 1985).

On the basis of the preliminary data from the study using mice (Maltoni, 1977), the EPA Carcinogen Assessment Group calculated estimated incremental excess cancer risk associated with exposure to 1,1-dichloroethylene in drinking water (U.S. EPA, 1984a,c). Assuming consumption of 2 liters of water by a 70 kg individual, it was estimated that exposure to 0.24 ug/l 1,1-dichloroethylene

over a lifetime would result in a one in a million risk rate (10^{-6}). Risks of 10^{-5} and 10^{-4} were estimated if exposure occurred at 2.4 or 24 ug/l, respectively.

IARC (1983) reported that the data were inadequate to assess the carcinogenic potential in humans, but that it would reevaluate this assessment after it had the opportunity to review the rat drinking water study (Rampy, et al., 1977; Quast, et al., 1983) and the NTP gavage bioassays (NTP, 1982).

Applying the criteria described in EPA's guidelines for assessment of carcinogenic risk (U.S. EPA, 1984b), 1,1-dichloroethylene may be classified in Group C: Possible human carcinogen. Group C includes agents with limited evidence of carcinogenicity in animals in the absence of human data.

VI. OTHER CRITERIA, GUIDANCE AND STANDARDS

- In June, 1984, EPA proposed a Recommended Maximum Contaminant Level (RMCL) of zero for 1,1-dichloroethylene in drinking water (U.S. EPA, 1984c). Promulgation of an RMCL is expected in late 1985.

- In 1980, EPA estimated a range of excess cancer risks for lifetime exposure to 1,1-dichloroethylene when developing ambient water quality criteria (U.S. EPA, 1980a). This range was 23 ug/l, 2.3 ug/l and 0.23 ug/l, respectively, for risks of 10^{-4}, 10^{-5} and 10^{-6}, assuming consumption of 2 liters of water and 6.5 grams of contaminated fish per day by 70 kg adult.

- The National Academy of Sciences calculated a chronic SNARL (Suggested-No-Adverse-Response-Level) of 100 ug/L, based upon non-carcinogenic effects only (NAS, 1983). The Academy identified a NOAEL of 2 mg/kg from the 1982 NTP bioassay in mice. An uncertainty factor of 100 was applied; it was assumed that a 70 kg adult consumes 2 liters of water daily and 20% of the exposure of most individuals would be from drinking water; in addition, a factor of 5/7 to correct from 5- to 7-day/week exposure.

- The World Health Organization has established a guideline for 1,1-dichloroethylene in drinking water of 0.3 ug/l, set on evidence of carcinogenicity (WHO, 1984).

- The threshold limit value (TLV) for occupational settings is 5 ppm (20 mg/m^3) (ACGIH, 1982).

VII. ANALYSIS

- Analysis of 1,1-dichloroethylene is by a purge-and-trap gas chromatographic procedure used for the determination of volatile organohalides in drinking water (Method 502.1. Volatile halogenated organic compounds in water by purge and trap gas chromatography. U.S. EPA, 1985a). This method calls for the bubbling of an inert gas through the sample and trapping 1,1-dichloroethylene on an adsorbant material. The adsorbant material is heated to drive off the 1,1-dichloroethylene onto a gas chromatographic column. This method is applicable to the measurement

UF(s) = uncertainty factors, based upon quality and nature of data

__L/day = assumed daily water consumption (1 or 2) in liters

One-day Health Advisory

The Jenkins, et al. (1972) study in which five liver or plasma enzyme activities were measured is considered to be appropriate for calculation of the One-day HA. Single oral doses of 100, 300 or 500 mg 1,1-DCE/kg in corn oil were administered to adult rats. Twenty-two to 46 hours after dosing with 100 mg/kg, liver glucose-6-phosphatase (G-6-P) was reduced to 80% of control; liver alkaline phosphatase (AP) was doubled. At 300 mg/kg, liver G-6-P was reduced to 53% of control, liver AP nearly quintupled, liver tyrosine transaminase quadrupled and plasma alkaline transaminase was elevated 150 percent. At 500 mg/kg, all four enzymes were affected further; in addition, plasma alkaline phosphatase was elevated more than 400 percent above control. The lowest dose administered (100 mg/kg) was identified as a LOAEL.

The one-day HA for the 10 kg child is calculated as follows:

$$\text{One-day HA} = \frac{(100 \text{ mg/kg/day})\ (10 \text{ kg})}{(100)\ (10)\ (1 \text{ L/day})} = 1.0 \text{ mg/L} = 1000 \text{ ug/L}$$

Where:

100 mg/kg/day = LOAEL

10 kg = assumed weight of protected individual

100 = uncertainty factor, appropriate for use with animal study

10 = uncertainty factor, appropriate for use in extrapolating LOAEL to NOAEL

1 L/day = assumed volume of drinking water consumed by 10 kg child

Ten-day Health Advisory

Appropriate studies for the calculation of the Ten-day HA are not available. However, evaluation of all toxicological data for 1,1-DCE suggests that the Longer-term Health Advisory for the 10 kg child would provide sufficient protection over a ten-day period as well. Thus, the Ten-day HA is 1000 ug/L.

Longer-term Health Advisory

A longer-term HA can be calculated from a 90-day subchronic study in which rats of both sexes were given 1,1-DCE at nominal concentrations of 0, 50, 100 or 200 ppm (0 to 25.6 mg/kg bw/day) in their drinking water (Rampy, et al., 1977). Except for a decrease in kidney:body weight ratio in males at the low dose, there were no statistically significant differences in organ weights or in organ:body weight ratios at the termination of the study. The only other

pathology noted was an increased cytoplasmic vacuolization of hepatocytes in the livers of both sexes exposed to the highest dose. A NOAEL of 100 ppm (10 to 12.6 mg/kg) was identified.

A Longer-term HA for the 10 kg child is calculated as follows:

$$\text{Longer-term HA} = \frac{(10 \text{ mg/kg/day})\ (10 \text{ kg})}{(100)\ (1 \text{ L/day})} = 1.0 \text{ mg/l} = 1000 \text{ ug/L}$$

Where:

10 mg/kg/day = NOAEL

10 kg = assumed weight of protected individual

100 = uncertainty factor, appropriate for use with animal data

1 L/day = assumed volume of water consumed by 10 kg child

A Longer-term HA for the 70 kg adult is calculated as follows:

$$\text{Longer-term HA} = \frac{(10 \text{ mg/kg/day})\ (70 \text{ kg})}{(100)\ (2 \text{ L/day})} = 3.5 \text{ mg/L} = 3500 \text{ ug/L}$$

Where:

all factors are the same except,

70 kg = assumed weight of protected individual

2 L/day = assumed volume of water consumed per day by 70 kg adult

Lifetime Health Advisory

The Lifetime HA can be calculated from the 2-year chronic study in rats (Quast, et al., 1983). 1,1-Dichloroethylene, at nominal concentrations of 0, 50, 100 or 200 ppm (0 to 20 mg/kg/day) in drinking water, was administered to animals of both sexes. No consistent treatment-related changes were observed in any parameter measured. The only histopathology observed was in the livers of both sexes receiving the highest dose, changes characterized by a minimal amount of mid-zonal fatty accumulation. No liver degeneration was noted. A LOAEL of 100 ppm (10 mg/kg) was identified, based upon a trend towards increased fatty deposition in the liver.

The Lifetime HA for the 70 kg adult is calculated as follows:

Step 1: Determination of RRfD*

$$\text{RRfD} = \frac{(10 \text{ mg/kg/day})}{(100)\ (10)} = 0.01 \text{ mg/kg/day}$$

- Reports of effects on workers exposed to this chemical in combination with other vinyl compounds include liver function abnormalities, headaches, vision problems, weakness, fatigue and neurological sensory disturbances (NIOSH, 1979).

Animals

Short-term Exposure

- Reported oral LD_{50}'s in adult rats range from 200 to 1800 mg/kg (NIOSH, 1978;Ponomarkov and Tomatis,1980). Young or fasted rats are more sensitive to the acute effects of administration, with LD_{50}'s of approximately 50 mg/kg (Andersen and Jenkins, 1977). The oral LD_{50}'s in the mouse and the dog were reported to be 200 mg/kg (Jones and Hathway, 1978b) and 5750 mg/kg (NIOSH, 1978), respectively.

- The most sensitive end-point of 1,1-DCE toxicity is liver damage, ranging from fatty infiltration to necrosis, although the mechanism appears to be different from that of other halogenated ethylenes (Reynolds, et al., 1975;Chieco, et al., 1982). The liver toxicity of 1,1-dichloroethylene follows a complex pattern of dose-response, with a threshold level, a concentration of rapid increase and an extended plateau where increasing doses cause little further increase in effect (Andersen and Jenkins, 1977).

- Kidney lesions also have been demonstrated following exposure to 1,1-dichloroethylene at doses similar to those affecting the liver (Prendergast, et al., 1967).

- The acute toxicity of the chemical is probably the result of a toxic metabolite rather than the parent compound (Andersen, et al., 1980).

Longer-term Exposure

- As with acute exposure, the liver appears to be the principal target of 1,1-dichloroethylene toxicity following extended periods of exposure. Chronic exposure of rats to levels up to 200 ppm (22 mg/kg) in drinking water resulted in fatty changes and hypertrophy of liver cells in females at all doses and in males at the highest dose (Rampy, et al., 1977;Quast, et al., 1983).

Teratogenic/Reproductive Effects

- 1,1-Dichloroethylene did not produce teratogenic effects in rats or rabbits following inhalation or drinking water exposure of dams during organogenesis (Murray, et al., 1979).

- Potential effects of 1,1-DCE on reproductive capacity have not been studied.

Mutagenicity

- 1,1-Dichloroethylene was mutagenic to bacteria in the Ames Salmonella test (Bartsch, et al., 1975, Simmon, et al., 1977) and E. coli (Greim, et al., 1975) in the presence, but not the absence, of a metabolic activation system.

- Mutation has not been confirmed in mammalian systems using V79 Chinese hamster ovary cells (Drevon and Kuroki, 1979) or dominant lethal tests in rats and mice (Anderson,1977; Andersen and Jenkins, 1977; Short, et al., 1977).

- 1,1-Dichloroethylene binds with DNA to a slight degree in the liver and kidneys of both rats and mice after inhalation exposure to 10 or 50 ppm for 6 hours (Reitz, et al., 1980). However, massive tissue damage also occurred.

- The International Agency for Research on Cancer (IARC) concluded that there is sufficient evidence to state that 1,1-dichloroethylene is mutagenic (IARC, 1983).

Carcinogenicity

- The results of most studies of the carcinogenic potential of this substance fail to support a significant, treatment-related increase in tumor incidence (U.S. EPA, 1984a). No oral study has resulted in a significant tumor response (NTP, 1982;Quast, et al., 1983). Some, but not all, of the inhalation studies have reported significant tumor increases (e.g., mammary tumors in female rats and mice and kidney adenocarcinomas in mice) (Maltoni, 1977; Maltoni, et al., in press).

- 1,1-Dichloroethylene was inactive as a whole mouse skin carcinogen when administered subcutaneously (Van Duuren, et al., 1979). It was active as a skin tumor initiator following several applications of phorbol ester as a promotor.

V. QUANTIFICATION OF TOXICOLOGICAL EFFECTS

Health Advisories are based upon the identification of adverse health effects associated with the most sensitive and meaningful non-carcinogenic end-point of toxicity. The induction of this effect is related to a particular exposure dose over a specified period of time, most often determined from the results of an experimental animal study. Traditional risk characterization methodology for threshold toxicants is applied in HA development. The general formula is as follows:

$$\frac{\text{(NOAEL or LOAEL) (BW)}}{\text{(UF(s)) (\_\_L/day)}} = \text{\_\_ ug/L}$$

Where: NOAEL or LOAEL = No-Observed-Adverse-Effect-Level
or
Lowest-Observed-Adverse-Effect-Level
(the exposure dose in mg/kg bw)

BW = assumed body weight of protected individual in kg (10 or 70)

Occurrence

- 1,1-Dichloroethylene (1,1-DCE) is a synthetic chemical with no natural sources (U.S. EPA, 1983).

- Approximately 200 million pounds of 1,1-dichloroethylene were produced in 1980. The major use of 1,1-dichloroethylene is as a co-monomer in the production of a number of polymers. Polymers of 1,1-dichloroethylene and vinyl chloride are used as food wrap (CEH, 1983).

- The major releases of 1,1-dichloroethylene to the environment are during its production and its use in the manufacture of polymers. Due to its volatile nature, the majority of releases are expected to be to air. Small amounts of 1,1-dichloroethylene may be released to water and land in industrial effluents and from the disposal of solid wastes (U.S. EPA, 1983). 1,1-Dichloroethylene may be a degradation product of trichloroethylene and perchloroethylene. While laboratory studies are currently inconclusive, 1,1-dichloroethylene has been found to co-occur in ground water with trichloroethylene and tetrachloroethylene and their other degradation products, cis- and trans-1,2-dichloroethylene and vinyl chloride.

- There is relatively little information on the behavior of 1,1-dichloroethylene in the environment. However, the behavior of this chemical has been estimated based upon the information on similar chlorinated compounds (U.S. EPA, 1979). 1,1-Dichloroethylene released to the atmosphere is expected to chemically degrade in a matter of hours; when released to surface waters, 1,1,-DCE is expected to volatilize rapidly to air. 1,1-Dichloroethylene is chemically stable in water and mobile in soils. Once released to land, 1,1-dichloroethylene is expected to migrate with ground water. 1,1-Dichloroethylene is not believed to bioaccumulate in plants or animals.

- Available data suggest that 1,1-dichloroethylene is not a common contaminant of drinking water. It has not been reported to occur at levels higher than 0.1 ug/L in surface water. However, 1,1-dichloroethylene has been reported to occur at levels up to 40 ug/L in wells contaminated with other chlorinated solvents.

- No information is available on the occurrence of 1,1-dichloroethylene in food. While 1,1-dichloroethylene is used in the manufacture of food wrap, residual levels are expected to be very low because of its high volatility. Little or no contamination of food is expected from this use. Because of limited release, rapid degradation and high volatility, 1,1-DCE is not expected to be a common contaminant in food.

- 1,1-Dichloroethylene contamination of air has been reported to occur in urban and suburban areas in the low ppt range. Levels in the ppb range have been reported in the areas where 1,1-DCE and its polymers are manufactured (U.S. EPA, 1983).

I. PHARMACOKINETICS

Absorption

- Administration of a single oral dose of 1,1-dichloroethylene in the range of 0.5 to 50 mg/kg resulted in rapid and complete absorption in rats and mice (Jones and Hathway, 1978a;McKenna, et al., 1978b).

Distribution

- Distribution in rats following a single oral dose of 25 mg 1,1-DCE/kg resulted in high concentrations in the liver and kidneys after 30 minutes with more general distribution throughout other soft tissues after 1 hour (Jones and Hathway, 1978a).

- Single oral doses of ^{14}C-1,1-DCE at 1 or 50 mg/kg were administered to rats (McKenna, et al., 1978a,b). At 72 hours after dosing, the greatest percentage of radioactivity was found in the liver.

Metabolism

- The metabolic end products of chlorinated ethylenes are predominately alcohols and carboxylic acids. The known metabolites of 1,1-dichloroethylene are chloroacetic acid and dichloroacetaldehyde (Liebler and Guengerich, 1983;Liebler, et al., 1984). Toxic intermediates that are formed may interact with tissue macromolecules.

- Metabolism is readily saturable at higher doses (McKenna, et al., 1978a,b), but presumably not so at levels expected to be encountered in contamination incidents.

Excretion

- The rate of excretion is relatively rapid, since most of a dose is eliminated within the first 24-72 hours after administration (Jaeger, et al., 1977). At low doses, most of the metabolites are eliminated via renal and biliary excretion. Carbon dioxide formed during metabolism is expired through the lungs.

- At higher dose levels, as metabolism reaches saturation, less of the compound is removed from the blood as it passes through the liver. As a result, increasing amounts of unchanged 1,1-dichloroethylene are eliminated via the lungs (McKenna, et al., 1977).

IV. HEALTH EFFECTS

Humans

- At high concentrations ($\geq$ 4000 ppm), inhalation of 1,1-dichloroethylene results in rapid onset of CNS depression, with unconsciousness following if exposure is continued (Irish, 1963).

September 30, 1985

1,1-DICHLOROETHYLENE

Health Advisory
Office of Drinking Water
.S. Environmental Protection Agency

ng Water's non-regulatory Health Advisory Program provides
ects, analytical methodology and treatment technology that
g with contamination of drinking water. Health Advisories
ons of contaminants in drinking water at which adverse
cipated to occur. A margin of safety is included to
s of the population.

e not legally enforceable Federal standards. They are
and better information becomes available. The Advisories
guidance to assist Federal, State and local officials
n of the public health.

numbers are developed from data describing non-carcinogen
They do not incorporate quantitatively any potential
ch exposure. For those chemicals which are known or
s according to the proposed Agency classification scheme,
and Longer-term Health Advisories may be derived, with
n Advisories for lifetime exposures may not be recommended.
cancer risks are provided to give an estimate of
contaminant which may pose a carcinogenic risk to
al estimates usually are presented as upper 95% confidence
linearized multistage model which is considered to be
the probable true risk.

SL 063124

This Health Advisory (HA) is based upon information presented in the Office of Drinking Water's Health Effects Criteria Document (CD) for the Dichloroethylenes (U.S. EPA, 1984a). The HA and CD formats are similar for easy reference. Individuals desiring further information on the toxicological data base or rationale for risk characterization should consult the CD. The CD is available for review at each EPA Regional Office of Drinking Water counterpart (e.g., Water Supply Branch or Drinking Water Branch), or for a fee from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA., 22161, PB #_____, $_____. The toll free number is (800) 336-4700; in Washington, D.C. area: (703) 437-4650.

II. General Information and Properties

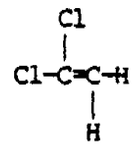
Synonyms

Vinylidene chloride, 1,1-DCE, dichloroethene

Uses

Chemical intermediate
Manufacture of polyvinylidene copolymers

Properties

CAS #	75-35-4
Chemical formula	$C_2H_2Cl_2$
Molecular weight	96.95
Physical state (room temp.)	clear, colorless liquid
Melting point	-122.2 °C
Boiling point	31.5 °C
Vapor pressure	591 torr (20°C)
Specific gravity	1.3
Water solubility	250,000 ug/L (20°C)
Octanol/water partition coefficient	5.37
Taste threshold (water)	-
Odor threshold (water)	-
Odor threshold (air)	2000-5500 mg/m^3
Structural formula	

(Irish, 1963; Windholz, et al., 1976)